



8-23-04

JFW RCE ✓

Patent and Trademark Office Docket No. U 014605-0

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: VLADIMIR NIKOLAEVICH PAK, et al
Application No.: 09/885,645 Group No.: 1642
Filed: JUNE 20, 2001 Examiner: SUSAN UNGAR
For: METHOD FOR TREATMENT OF MALIGNANT NEOPLASMS AND A
COMPLEX PREPARATION HAVING ANTIMALIGNANT ACTIVITY

Mail Stop RCE
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CONTINUED EXAMINATION (RCE)
(37 C.F.R. 1.114)

1. Applicant hereby requests continued examination, in accordance with 37 C.F.R. Section 1.114, for the above identified application.

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) AND 1.10
(When using Express Mail, the Express Mail label number is mandatory;
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

- ☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.
37 C.F.R. Section 1.8(a) TRADE 37 C.F.R. Section 1.10
- ☐ with sufficient postage as first class mail. ☒ as "Express Mail Post Office to Addressee"
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TRANSMISSION

- ☐ facsimile transmitted to the Patent and Trademark Office to (703) 872-9306

Date: August 20, 2004

GERALDINE MARTII

Signature

(type or print name of person certifying)

• Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

08/24/2004 SSITHIB1 00000114 09885645

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385.00 OP

NOTE: 37 C.F.R. § 1.114 Request for continued examination:

"(a) If prosecution in an application is closed, an applicant may request continued examination of the application by filing a submission and the fee set forth in § 1.17(e) prior to the earliest of:

(1) Payment of the issue fee, unless a petition under § 1.313 is granted;

(2) Abandonment of the application; or

(3) The filing of a notice of appeal to the U.S. Court of Appeals for the Federal Circuit under 35 U.S.C. 141, or the commencement of a civil action under 35 U.S.C. 145 or 146, unless the appeal or civil action is terminated.

(b) Prosecution in an application is closed as used in this section means that the application is under appeal, or that the last Office action is a final action (§ 1.113), a notice of allowance (§ 1.311), or an action that otherwise closes prosecution in the application.

(c) A submission as used in this section includes, but is not limited to, an information disclosure statement, an amendment to the written description, claims, or drawings, new arguments, or new evidence in support of patentability. If reply to an Office action under 35 U.S.C. 132 is outstanding, the submission must meet the reply requirements of § 1.111.

(d) If an applicant timely files a submission and fee set forth in § 1.17(e), the Office will withdraw the finality of any Office action and the submission will be entered and considered. If an applicant files a request for continued examination under this section after appeal, but prior to a decision on the appeal, it will be treated as a request to withdraw the appeal and to reopen prosecution of the application before the examiner. An appeal brief under § 1.192 or a reply brief under § 1.193(b), or related papers, will not be considered a submission under this section."

NOTE: An applicant may file a submission under 37 C.F.R. 1.114 containing only an information disclosure statement (37 C.F.R. 1.97 and 1.98) in an application subject to a notice of allowance under 35 U.S.C. § 151. An appeal brief or a reply brief (or related papers) will not be considered a submission under 37 C.F.R. 1.114. See 37 C.F.R. 1.114(d). The submission, however, may consist of the arguments in a previously filed appeal brief or reply brief, or may simply consist of a statement that incorporates by reference the arguments in a previously filed appeal brief or reply brief. In addition, a previously filed amendment after final may satisfy this submission requirement. American inventor's Protection act of 1999, Question & Answer A5.

NOTE: Even though an RCE is improper (e.g., because it was filed before the prosecution is closed), an amendment submitted with the RCE will still be entered and considered by the examiner since it was timely filed and responsive to the non-final Office action in compliance with 37 C.F.R. 1.111. American Inventor's Protection Act of 1999, Question & Answer A4.

WARNING: 35 U.S.C. 132(b) and Section 1.114 provide for the continued examination of an application and **not** examination of a continuing application). Accordingly, the Office will not permit an applicant to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined. Notice of March 10, 2000, 65 Fed Reg 14865, at 14868.

WARNING: The provisions of 37 C.F.R. 1.114 also do not apply (1) to a provisional application; (2) an application for a utility or plant patent filed under 35 U.S.C. 111(a) before June 8, 1995; (3) an international application filed under 35 U.S.C. 363 before June 8, 1995 (4) a patent under reexamination or (5) an application for a design patent. 37 C.F.R. § 1.114(e).

WARNING: The PTO has pointed out why § 1.97(b) does not provide that an information disclosure statement will be considered if it is filed within three months after the date of a request for continued examination under § 1.114. The PTO explained that since an RCE filing is a reply under 35 U.S.C. 132, the applicant may be entitled to patent term adjustment if the Office does not act on an application containing a request for continued examination under § 1.114 within four months. See 35 U.S.C. 154(b)(1)(A)(ii). Thus, the Office cannot delay action on RCE applications for three months to determine whether an information disclosure statement will be filed. The Office, however, is adopting provisions (§ 1.103(c)) for a limited suspension of action after the filing of a request for continued examination under § 1.114, for the applicant to obtain additional time (prior to the issuance of the next Office action) to provide an information disclosure statement (or amendments, or an affidavit or declaration) after the filing of the RCE. See Notice of August 16, 2000, "Request for Continued Examination Practice and Changes to Provisional Application Practice; Final Rule", 65 Fed. Reg., pages 50091-50105, at page 50100 (comment 11); OG: September 5, 2000, pages 13-24.

WARNING: One of the time periods excluded from patent term adjustment is the time consumed by a continued examination request under 35 U.S.C. 132(b) (§ 1.114(b)(1)).

WARNING: The Office will not suspend action in an application when a reply by the applicant is outstanding. 35 U.S.C. 133 requires an applicant to "prosecute the application" within six months of an Office action (or a shorter period as set in the Office action) to avoid abandonment of the application. If an applicant files a request for continued examination but does not also provide any submission (in reply to the prior Office action) within the period for reply to the prior Office action, the application is abandoned by operation of law (35 U.S.C. 133).

The Office will treat a request for continued examination under § 1.114 containing a bona fide submission that is not fully responsive to the prior Office action under the practice set forth in § 1.135(c). In addition, under the limited suspension of action provisions of § 1.103(c), an applicant must still file a request for continued examination practice in compliance with § 1.114, but may obtain additional time (prior to the issuance of the next Office action) to provide an information disclosure statement, amendments, or an affidavit or declaration after the filing of the request for continued examination.

See Notice of August 16, 2000. "Request for Continued Examination Practice and Changes to Provisional Application Practice; Final Rule", 65 Fed. Reg., pages 50091-50105, at page 50102 (comment 20); OG: September 5, 29000, ages 13-24, Page 50102.

WARNING: Section 197(b) does not provide that an information disclosure statement will be considered if it is filed within three months after the date of request for continued examination under § 1.114.

NOTE: There is no limit to the number of times the fee for continued examination may be submitted. Notice of March 10, 2000, 65 Fed. Reg. 14865. at 14868.

NOTE: Unlike a continuation application, a continued examination request **can** utilize the mailing procedure of 37 C.F.R. 1.8. See 37 C.F.R. Section 1.8(a)(2)(i)(A).

TIME REQUEST IS BEING MADE

2. This request is being submitted (check appropriate item(s) below):

- i. ☒ Prior to abandonment of the application
- ii. ☒ Payment of the issue fee
 - ☒ Prior to payment of issue fee
 - ☐ Issue fee has been paid but a petition under Section 1.313 has been granted
- iii. ☒ Prior to a decision on appeal to the Board of Patent Appeals & Interferences
 - ☐ A notice is being separately sent to the Board of Patent Appeals & Interferences that this Request for Continued Examination is being filed.
- iv. ☒ Appeal to the U.S. Court of Appeals of the Federal Circuit under 35 U.S.C. 145 or Commencement of a civil action under 35 U.S.C. 146
 - ☒ Prior to the filing of such appeal or commencement of civil action
 - ☐ Such appeal or commencement of civil action has been terminated

NOTE: If such a notice is not sent to the Board, they may refuse to vacate a decision rendered after the filing of the RCE but before recognition by the Office of the RCE request under Section 1.114.

ENCLOSURES

3. Do not automatically enter any prior unentered amendment(s). Herewith as the required submission is/are:

- ☐ Request hereby to enter unentered amendment(s) of _____
- ☐ An information disclosure (37 C.F.R. Section 1.98)
☐ Form PTO-1449 (PTO/SB/08A and 08B)
- ☒ An amendment
- ☐ New arguments
- ☐ New evidence in support of patentability

WARNING: *If reply to a final or non-final Office action under 35 U.S.C. 132 is outstanding, the submission must meet the reply requirements of Section 1.111. 37 C.F.R. Section 1.114(b).*

- ☒ Other
TWO DECLARATIONS OF VLADIMIR PAK

FEE FOR REQUEST (37 C.F.R. Section 1.17(e)).

4. This application is on behalf of:

- | | | |
|-------------------------------------|--|------------------|
| <input checked="" type="checkbox"/> | Small entity (and status is still as small entity) | \$ 385.00 |
| <input type="checkbox"/> | Other than a small entity | \$ 770.00 |
| | Continued Prosecution Request Fee | <u>\$ 385.00</u> |

FEE FOR CLAIMS

NOTE: *"The fee for continued examination under Section 1.114 (Section 1.17(e)) does not include additional claims fee (cf. 1.53 (d)(3)(ii))." See Notice of March 10, 2000, 65 Fed Reg 14865, at 14868.*

37 C.F.R. 1.53(d)(3) : *"The filing fee for a continued prosecution application filed under this paragraph is:*

(i) The basic filing fee as set forth in Section 1.16; and

(ii) Any additional Section 1.16 fee due based on the number of claims remaining in the application after entry of any amendment accompanying the request for an application under this paragraph and entry of any amendments under Section 1.116 unentered in the prior application which applicant has requested to be entered in the continued prosecution application."

5. The fee for claims (37 C.F.R. Section 1.16(b)-(d)) has been calculated as shown below:

						OTHER THAN A SMALL ENTITY			
(Col. 1)		(Col. 2)		(Col. 3)	SMALL ENTITY				
Claims Remaining After Amendment		Highest No. Previously Paid For		Present Extra	Rate	Addit. Fee	OR	Rate	Addit. Fee
Total	*	Minus	**	=	x \$9 =	\$		x \$18 =	\$
Indep.	*	Minus	***	=	x \$43 =	\$		x \$86 =	\$
[] First Presentation of Multiple Dependent Claim					+ \$145 =	\$		+ \$290 =	\$
					Total Addit. Fee	\$	OR	Total Addit. Fee	\$

* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3,

** If the "Highest No. Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest No. Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest No. Previously Paid For" (Total or Indep.) is the highest number found in the appropriate box in Col. 1 of a prior amendment or the number of claims originally filed.

WARNING: See 37 C.F.R. Section 1.116.

EXTENSION OF TIME

(If an extension of time is appropriate complete (a) or (b), as applicable)

6. The proceedings herein are for a patent application, and the provisions of 37 C.F.R. Section 1.136(a) apply.

(a) [X] Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. Section 1.17(a)(1)-(4), for the total number of months checked below:

Extension for (months)	Fee for other than small entity	Fee for small entity
[] one month	\$ 110.00	\$ 55.00
[X] two months	\$ 420.00	\$ 210.00
[] three months	\$ 950.00	\$ 475.00
[] four months	\$ 1,480.00	\$ 740.00

Fee \$ 210.00

If an additional extension of time is required, please consider this a petition therefor.

(check and complete the next item, if applicable)

- ☐ An extension for _____ months has already been secured, and the fee paid therefor of \$ _____ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ _____

OR

- (b) ☐ Applicant believes that no extension of time is required. However, this is a conditional petition and authorization to pay the necessary fees to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

TOTAL FEE(S) DUE

WARNING: The fee for continued examination under Section 1.114 may not be deferred. 37 C.F.R. Section 1.53(f).

7. The total fee(s) due is/are:

Continued Prosecution Fee (Section 1.17(e)) \$ 385.00

Fee(s) for additional claims (if any) (Section 1.16(b)-(d)) \$ _____

Extension of time fee (if any) (Section 1.17(a)(1)-(4)) \$ 210.00

Total Fee(s) Due: \$ 595.00

PAYMENT OF FEE(S) DUE

8. Please pay the fee(s) for this continued examination application as follows:

☒ Check is attached for the sum of \$ 595.00

☐ Charge Account _____ the sum of \$ _____

Please charge any required additional fee(s) for Section 1.17(e), Section 1.16(b)-(d) and/or Section 1.17(a)(1)-(4) or refund overpayment to

☒ Deposit Account 12-0425

INVENTORSHIP

NOTE: Any change of inventors must be via the procedure set forth in 37 C.F.R. Section 1.48. See Notice of March 10, 2000, 65 Fed Reg 14865, at 14868.

9. This application as amended names as inventors:

- ☐ the same inventors as previously designated for the claims.
- ☐ fewer than the inventors previously designated and a statement accompanies this request for the deletion of the name or names of the person or persons who are not inventors of the invention now being claimed.
- ☐ a person not named previously as an inventor and a petition under 37 C.F.R. Section 1.48 is/has separately:
 - ☐ being filed
 - ☐ been filed

DEFERRAL OF EXAMINATION

10. ☐ A Request for Suspension of examination accompanies this request for continued examination. *(See, 9-68 or Petition for Suspension)*



SIGNATURE OF PRACTITIONER

Reg. No.: 33,778

JANET I. CORD

(type or print name of practitioner)

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c/o Ladas & Parry LLP
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New York, N.Y. 10023



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: **VLADIMIR NIKOLAEVICH PAK, et al**

Application No.: 09/885,645

Group No.: 1642

Filed: JUNE 20, 2001

Examiner: SUSAN UNGAR

For: **METHOD FOR TREATMENT OF MALIGNANT NEOPLASMS AND A
COMPLEX PREPARATION HAVING ANTIMALIGNANT ACTIVITY**

**Mail Stop RCE
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450**

PRELIMINARY AMENDMENT

Please amend the above-identified application as follows:

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10*

*(When using Express Mail, the Express Mail label number is **mandatory**;
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

37 C.F.R. 1.8(a)

☐ with sufficient postage as first class mail.

37 C.F.R. 1.10*

☒ as "Express Mail Post Office to Addressee"
Mailing Label No. EV 481669774 US

(mandatory)

TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.

Geraldine Marti
Signature

Date: August 20, 2004

GERALDINE MARTI
(type or print name of person certifying)

***WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).

*"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*